REQUEST & CERTIFICATION FOR RESEARCH PROCUREMENT OF HUMAN BIOLOGICAL MATERIALS [NIH 2803-1 (11-02)]

(ELECTRONIC FORM INSTRUCTIONS)

This form is designed to be filled out on page one and will automatically populate the data into the 2nd and 3rd copy of the form when printed. The form is locked and password protected to prevent modification, however use care when entering data to prevent format changes to the tables. Use the "Tab" key to go from field to field.

If all three copies need to be printed, print the file without specifying which page. If only the 1st and/or 3rd (optional) page are needed, indicate the page numbers to print under the File menu, Print option.

Note: In order for the fields to update on each copy, when printing, the "Update Field" option must be flagged as a print option.

- *If you are using a PC: Go to File → Print and select the Options tab at the bottom of the palette. Make sure the Update Fields checkbox is checked.*
- *If you are using a Mac, Go to File → Print Click the menu, which reads General, and select Microsoft Word. From there select the Word Options button and make sure Update Fields checkbox is checked.*

You may wish to save your document under a different name. To keep the original settings, select "No" when asked, "Do you want to save changes?"

Data Entry:

Note: You may leave certain fields blank (e.g., dates, etc) if you are printing multiple forms for the future, and hand write this information on each copy.

1. Enter the IRB Protocol Number and its designated PI (first and last name).
2. Add the designated PI's telephone number and pager so he/she may be contacted if needed.
3. Indicate the date of the request.
4. Check only <u>one</u> box to specify if the specimen(s) are:
   a. Procured (collected) for "Research Use Only", <u>or</u>
   b. If specimens are for both "Research and Diagnostic/Transplant Purposes (e.g., split sample between research and clinical).
5. Indicate the description of the anticipated research sample(s) and the corresponding name of recipient, phone, pager, and location.
6. The principal investigator (PI), or an associate investigator (AI), <u>specified in writing on the IRB protocol</u> will need to sign the request after it is printed. You may enter the name to the left of the signature and record date, if you know this in advance.
7. Check the appropriate box or boxes to indicate how or where the materials are released (for tracking/retrieval purposes), if you know this in advance.
   a. Delivery to Principal Investigator or lab; check this box if the material is given to a researcher designated in the protocol.
   b. Delivery to Research Recipient or lab; check this box if the material is given to a researcher, other than the PI.

c. By CC Patient Escort Services; check this box when the CC Patient Escort Services transport material. Patient Escort Services maintains a log of all deliveries.
d. By Other Courier; check this box if research team uses a standard contracted courier. Research team should be able to track specimens if necessary through the courier.
e. Other (specify); check this box, if appropriate, and specify enough information so that specimen may be tracked if necessary.

After printing the form:

8. Print one form for each procurement procedure. Please do not make photocopies of the form because, copies do not create high quality microfiche images when medical records are archived.
9. Provide patient identification information (last name, first name, middle initial, NIH medical record number) in the lower left hand corner EACH COPY of the form.
10. Make sure all parts of the form are complete.
11. The principal investigator (PI), or an associate investigator (AI), specified in writing on the IRB protocol must sign the request. This certifies that the specified IRB approval covers both the protocol and patient-executed consent, and that the research proposed is specified with the approved protocol and consent documents. Be sure to enter name to the left of the signature and record date.
12. Check the appropriate box or boxes to indicate how or where the materials are released (for tracking/retrieval purposes). See step 7 for explanation of boxes.
13. The person releasing the materials (e.g., PI, AI, MD, researcher, nurse, technologist, technician, etc.) must indicate method of release and sign the form. Do not ask a courier or escort to sign this section. Be sure to enter the name to the left of the signature line, and record date.
14. Distribute the forms to the appropriate destination after signatures on all copies are obtained.
    a. If specimen was acquired for "Research Use Only":
        i. Place original copy in Medical Record or send to 10/1N208.
        ii. Retain 3rd copy for Research team (optional).
    b. If specimen was acquired for both "Research and Diagnostic/Transplant Purposes:
        i. Place original top copy in Medical Record or send to 10/1N208.
        ii. Send 2nd copy with the specimen to the diagnostic lab or to the transplant bank.
        iii. Retain 3rd copy for Research team (optional).